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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,072	12/04/2003	Ron Heil	GUID.626PA	7645
51294	7590	05/12/2005	EXAMINER	
CRAWFORD MAUNU PLLC 1270 NORTHLAND DRIVE SUITE 390 ST. PAUL, MN 55120			GREENE, DANA D	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,072

Applicant(s)

HEIL ET AL.

Examiner

Dana D. Greene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/4/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/04/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/5/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-42, 44-55, and 63-66 stand rejected under 35 U.S.C. §102(b) as being anticipated by Altman et al. (US 6,416,510, hereinafter "Altman"). Altman is considered to disclose:

an implantable cardiac lead, comprising a lead body (see col. 7, ln. 35-41 and col. 10, ln. 4-10, Altman). The disclosed catheter is considered to anticipate the claimed cardiac lead because both devices extend into the patient's heart and connect with electrodes that contact the myocardium for sensing the heart's electrical signals;

an electrode supported by the lead body, the electrode configured for subcutaneous non-intrathoracic placement within a patient (see col. 10, ln. 4-10 and col. 16, ln. 18-30, Altman). The disclosed electrode is considered to anticipate the claimed electrode because both are position ally stabilized within the subcutaneous tissue surrounding the catheter or the lead;

a driving arrangement coupled to the lead, the driving arrangement configured to provide phoresis delivery of a pharmacological agent from the lead to subcutaneous tissue (see col. 6, ln. 50-60, Altman). The claimed drug delivery system is considered to

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anticipate the claimed driving arrangement because both are able to actively transmit pharmacological agents into the surrounding tissue.

With reference to claim 4, Altman is considered to disclose the claimed invention as discussed above including an electrode array (see col. 19, ln. 1-15, Altman). The disclosed device is considered to anticipate the claimed electrode array because both devices are capable of sensing cardiac activity and delivering cardiac stimulation energy.

With reference to claim 5, Altman is considered to disclose the claimed invention as discussed above including the conductor (see col. 11, ln. 45-50, Altman). The disclosed conductor is considered to anticipate the claimed conductor because both devices must be present for the deliver of pharmacological agents to monitor the electrical action of the heart.

Referring to claims 10-12 and 25-26, Altman is considered to disclose the claimed invention as discussed above including the porous region and the polymeric structure (see col. 6, ln. 56-65, Altman). The disclosed polymer substrate is considered to anticipate the claimed porous region because both configurations allow for the application of an electric field across the polymer substrate and the incorporation of the pharmacological agents with the lead.

With reference to claims 13-17, 29-32, 44-47, 50-54, and 63-66 Altman is considered to disclose the claimed invention as discussed above including the therapeutic treatment in the form of an anesthetic, anti-inflammatory, antiseptic, or agent providing vasoconstriction (see col. 2, ln. 1-65, Altman).

With reference to claims 18-24 and 55-58, Altman is considered to disclose the claimed invention as discussed above including:

a can coupled to the lead, the can configured to provide phoresis delivery of a pharmacological agent from at least a portion of the can to subcutaneous tissue (see col. 19, ln. 10-15, Altman). The disclosed device is considered to anticipate the claimed can because both configurations are capable of having pharmacological agents for subsequent distribution.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. §103(a) as being unpatentable over Altman in view of Gray (US 6,144,879, hereinafter "Gray"). Altman is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the

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claimed transducer. However, Gray is considered to disclose the claimed transducer (see col. 5, ln. 36-50, Gray). It would have been obvious to one of ordinary skill in the art to combine the teachings of Altman with the transducer taught in Gray for the purpose of converting one form of energy to another.

Claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Altman in view of Stokes (US 4,506,680, hereinafter "Stokes"). Altman is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed sheath. However, Stokes is considered to disclose the claimed sheath (see col. 2, ln. 30-50, Stokes). It would have been obvious to one of ordinary skill in the art to combine the teachings of Altman with the sheath taught in Stokes for the purpose of providing a sheath and inserting the lead into the sheath to deliver the lead into subcutaneous non-intrathoracic tissue.

Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Altman in view of Schroepfel et al. (US 5,749,909, hereinafter "Schroepfel"). Altman is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed power signal voltages and frequency. However, Schroepfel is considered to teach the claimed voltages and frequency (see col. 2, ln. 35-50 and col. 8, ln. 47-64, Schroepfel). It would have been obvious to one of ordinary skill in the art to combine the teachings of Altman with the energy transmission system of Schroepfel for the purpose of driving the pharmacological agent using sonophoresis and applying a direct current (DC) signal to create an electric field in the tissue capable of driving the pharmacological agent using electrophoresis.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-7138. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-0276.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Dana D. Greene


George Manuel
Primary Examiner